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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/037,990 | 01/03/2002 | Vijay Sharma | RELIA P-106 | 7830 |

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EXAMINER

WORTMAN, DONNA C

ART UNIT PAPER NUMBER

1648

DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/037,990

Applicant(s)

SHARMA ET AL.

Examiner

Donna C. Wortman, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Claims 1-25 were canceled, claims 26, 32, 34, and 36 were amended, and claim 38 was added in Paper No. 7. Claims 26-38 are pending and under examination.

Claim 38 is objected to because of the following informalities: At line 13 and at line 14 of claim 38, "fluorescein" is misspelled. Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is indefinite in reciting "a first oligonucleotide primer (SEQ ID NO.1)"; "a second oligonucleotide primer (SEQ ID NO.2)"; and "an oligonucleotide probe (SEQ ID NO.3)", since it is not clear whether the sequence identification numbers in parentheses are intended to indicate that the primers and the probe are those that correspond identically to the respective sequence identification numbers, or whether the material in parentheses is intended to be an example of suitable primers and probes. The claim could be clarified by replacing the parentheses by commas, for example, if it is intended to recite the specific primers and probes that correspond to SEQ ID NO.1, NO.2 and NO.3, respectively.

Claims 26-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,580,718 to Resnick et al. in view of Geiger et al., essentially for reasons of record in rejecting claims 26-37 in the previous Office action. Resnick discloses a primer having SEQ ID NO:5, which is identical to SEQ ID NO:1 as instantly claimed,

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and a primer having SEQ ID NO:18, which is identical to SEQ ID NO:2 as instantly claimed, as well as methods using RNA dependent RNA polymerase, such as avian myeloblastosis polymerase, for reverse transcription and Taq polymerase for amplification (see, e.g., col. 15, line 35-col. 16, line 17). Resnick teaches amplification of HCV nucleic acids using the disclosed primers, as well as detection of amplified nucleic acids using probes that hybridize to the amplified HCV nucleic acid. Resnick teaches kits, reagents, and assay formats and conditions for performing such detection assays and teaches the use of probes, preferably labeled, directly or indirectly, that hybridize to amplified regions conserved across strains, but does not teach the specific probe having SEQ ID NO:3. Geiger teaches an HCV-specific probe that has SEQ ID NO:3. It would have been obvious to one of ordinary skill in the art to have substituted the HCV-specific probe that has SEQ ID NO:3 of Geiger for the probes of Resnick for expected equivalent results because Resnick discloses that a probe that hybridizes to a conserved region that lies between the two primers is suitable and because Geiger discloses that the HCV probe having SEQ ID NO:10, corresponding identically to Applicant's SEQ ID NO:3 probe, is suitable for the specific detection of HCV nucleic acid.

Applicant has argued that, absent Applicants' disclosure, there is no reasonable expectation that substituting the Geiger probe for the Resnick probe would result in successful RT-PCR as neither reference provides the reaction conditions of the present inventions; e.g., Resnick does not provide for the amplification component, and optimal reaction conditions (incubation times, temperatures, concentration of Taq DNA

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Polymerase, primers, MgCl₂, and template DNA) vary depending on the primers and probe being used; and that Applicants have discovered that the combination of primers and probe may be used for HCV diagnosis with high sensitivity, high specificity, rapid results, and high reproducibility.

These arguments have been considered but not found persuasive. Resnick provides a method using the same primers, the same commercially available avian myeloblastosis transcriptase and Taq polymerase, and the same conventional reagents, including buffers, as Applicant's method, and points out that sequence specific oligonucleotide probes are to be used to detect the presence of the amplified DNA. Further, no evidence has been presented that would indicate that sensitive, specific, rapid, reproducible detection of HCV is anything other than would be expected based on the teachings of Resnick and Geiger, since both teach specific detection of HCV nucleic acid and since Resnick teaches all the elements of Applicant's method except for the probe corresponding to SEQ ID NO:3, which is taught by Geiger as being specific for HCV. No evidence has been presented that would indicate that the claimed reagent concentrations for these known, commercially available reagents and procedures used are anything other than conventional amounts as known in the art. Other elements of Applicant's arguments (incubation times, temperatures) are features not actually found in the claims; however, the disclosed assay conditions do not appear to differ from the conventional.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'DCW', is positioned above the printed name.

Donna C. Wortman, Ph.D.
Primary Examiner
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dcw
February 26, 2003